

## **REMARKS**

### Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and arguments set forth is respectfully requested.

Claims 1-2, 4-17 and 26 are pending and under consideration. The Specification has been amended as explained below. No new matter has been added as a result of this amendment.

### Rejection of Claims 1-17 and 26 Under 35 U.S.C. § 112, First Paragraph

Claims 1-17 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

Specifically, the Examiner states that the specification fails to disclose the "unconjugated" large polycation as recited in the claims. The Examiner further states that description of an "unconjugated" large polycation is required in the specification.

Applicants' arguments in the previous Amendment are incorporated herein.

As pointed out in the previous Amendment, the polycation described in the instant application is "unconjugated" as defined in both general and technical dictionaries and as also understood by one skilled in the art.

Applicants will now point out the basis for support in the specification for "unconjugated".

On page 6, lines 3-10, the specification discloses that by a "large" polycation it is meant a polycation with a molecular weight of approximately 3,000 daltons or greater. Examples of large polycations are polylysines with a

molecular weight ranging between 5,200 and 11,200, polyornithine with a molecular weight of 5300, polybrene with a molecular weight ranging between 4,000 and 6,000, and MERQUAT<sup>TM</sup> with a molecular weight of approximately 4,000,000 daltons. It is further stated that the polycation can be added during the immunoassay as a separate reagent and alternatively, the polycation can be incorporated into an assay specific diluent.

Applicants submit that this passage clearly indicates that the large polycation as described in the instant invention is unconjugated. The molecular weight ranges of polylysine, polyornithine, polybrene and MERQUAT<sup>TM</sup> do not indicate that they are large enough to cover these large polycations conjugated to other molecules.

Additionally, the phrases "The polycation can be added during the immunoassay as a separate reagent" (emphasis added) and "Alternatively, the polycation can be incorporated into an assay specific diluent" (emphasis added) (See the specification, page 6, lines 9-10), clearly indicate that the large polycation is unconjugated. If the large polycation were conjugated, it would not be added as a separate reagent and incorporated into a diluent.

As a result, Applicants have amended the specification at page 6, line 10, to recite "Therefore, the polycation is unconjugated." in order to make this clear, as suggested by the Examiner.

The specification and more particularly, the Examples disclosed in the specification, do not suggest that the large polycation as used in the instant invention is conjugated. The conjugated molecules described therein do not pertain to the polycation.

On page 7, lines 1-7, the specification provides examples of labeled reagents such as a labeled antigen or antibody. However, these "conjugated" molecules are used in the binding assay for detecting the analyte of interest and do not pertain to the large polycation.

On page 8, lines 22-27, the specification describes the use of the large polycation in a PSA assay. The polycation is contained in a diluent. The acridinium-labeled conjugate is conjugated to the anti-PSA monoclonal antibody

and not the polycation. Additionally, the specification provides a separate kit component for the polycation (page 9, lines 2-3).

Example 1 describes the preparation of contaminated plasma or serum samples.

Example 2 describes the effect of the large polycations in an ARCHITECT™ TSH assay. The anti-TSH antibody is conjugated to the TSH and not the polycations (page 10, lines 4-5). Additionally, an acridinium label is conjugated to the anti- $\alpha$  TSH and not the polycations (page 10, lines 5-6). Therefore, any conjugated molecules described are used directly for the TSH assay and not for the large polycations with respect to decreasing interference (page 10, lines 12-18).

Example 3 describes the effect of the large polycations in an ARCHITECT™ free PSA assay. The free PSA present in the sample binds to the anti-free PSA coated microparticles and not the large polycations (page 11, lines 18-19). Additionally, an anti-PSA acridinium-labeled conjugate is used but is not conjugated to the large polycations (page 11, lines 19-20 and lines 26-28).

Finally, Example 4 describes the effect of the large polycations in an ARCHITECT™ total PSA assay. Monoclonal antibodies are used in a similar manner as described in Example 3, but bind to both free and complexed PSA and not the large polycations (page 12, lines 16-22).

Therefore, it is clear from the specification that the large polycations used in the instant invention are in an unconjugated form.

For the above reasons, Applicants respectfully request withdrawal of the rejection of claims 1-17 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Rejection of Claims 1 and 7 Under 35 U.S.C. § 102(b)

Claims 1 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Siedel *et al.* (herein “Siedel”), U.S. Patent Number 5,288,606.

The Examiner reiterates the rejection made in the previous Office Action. Applicants respectfully traverse the rejection. Applicants’ arguments in the previous Amendments are incorporated herein. Additionally, Applicants would like to respectfully point out the following to the Examiner with respect to the Siedel reference.

Siedel discloses a process and reagents for specific determination of fructosamine. Siedel does not disclose nor suggest using a large, unconjugated polycation for decreasing interference in an assay. Moreover, Siedel does not disclose nor suggest using polylysine, polyornithine, polybrene or dimethyldiallylammonium chloride as a large, unconjugated polycation for decreasing interference in an assay.

Applicants would like to respectfully remind the Examiner that in the previous Office Action, the Examiner stated that claim 3 was free of the prior art. In Applicants’ previous Amendment, claim 3 was canceled and the subject matter of claim 3 was added in claim 1. Claim 7 is dependent on claim 1.

Therefore, Applicants respectfully request withdrawal of the rejection of claims 1 and 7 under 35 U.S.C. § 102(b) as being anticipated by Siedel *et al.*, U.S. Patent Number 5,288,606.

## CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 112 and 102. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

R. Scoop, et al.



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